

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/595,095	Confirmation No.:	2491
Applicant	:	UDIPI, Kishore		
Filed	:	February 9, 2006		
TC/A.U.	:	1612		
Examiner	:	GULLEDGE, Brian M.		
Docket No.	:	P1366 US		
Customer No.	:	28390		
Title	:	BIOCOMPATIBLE CONTROLLED RELEASE COATINGS FOR MEDICAL DEVICES AND RELATED METHODS		

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

In response to the Office Action mailed June 7, 2010, please amend the above-identified application as set forth below.

Remarks/Arguments begin on page 2 of this paper.

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested.

Previous Office Action

Applicant's current Representatives have done further analysis into the facts supporting the 103(c) statement made in the Amendment filed February 10, 2010 regarding Lyu et al. (US Pub. 2004/0047911). Based on the facts obtained to date, it is not entirely clear that this is a valid statement. Accordingly, Applicant's withdraw the 103(c) statement and reserve the right to present additional arguments to overcome any rejections based on Lyu et al. (US Pub. 2004/0047911) in the event they are reinstated.

35 U.S.C. §103 Rejections

The Examiner rejected claims 1-13 and 15-21 under 35 U.S.C. §103(a) as being unpatentable over Benz et al. (U.S. Publication No. 2003/0162905 A1) in view of Shalaby et al. (U.S. Publication No. 2003/0199964 A1) and Van Krevelen ("Properties of Polymers," 1990, Elsevier, 3rd Edition, Chapter 7, pgs. 189-225). The Examiner rejected claims 14 and 22-24 under 35 U.S.C. §103(a) as being unpatentable over Benz et al. (U.S. Publication No. 2003/0162905 A1) in view of Shalaby et al. (U.S. Publication No. 2003/0199964 A1) and Van Krevelen ("Properties of Polymers," 1990, Elsevier, 3rd Edition, Chapter 7, pgs. 189-225), as applied to claim 13, and further in view of Sirhan et al. (U.S. Publication No. 2002/0082677 A1). These rejections are respectfully traversed.

It is respectfully submitted that the Examiner has made mere conclusory statements without providing a required rationale for the combination of cited documents. That is, the Examiner has described specific teachings of each of the cited documents but has not provided a rationale that links these teachings and the asserted conclusion of obviousness other than the "idea for combining them flows logically from their having been individually taught in the prior art" (page 3 to 4 of the Office Action).

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 167 L. Ed. 2d 705, 82 USPQ2d (BNA) 1385 (2007), the U.S. Supreme Court stated that "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Furthermore, the U.S. Supreme Court acknowledged that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art.” *Id.* at 418, 127 S. Ct. 1741, 167 L. Ed. 2d at 722, 82 USPQ2d (BNA) at 1389.

In the present Office Action, this is precisely what has occurred – various elements of the claims have been extracted from the jungle of prior art in the polymer blends and medical device fields without an articulated reasoning and some rationale beyond merely stating that these elements exist. This is insufficient to meet a *prima facie* case of obviousness.

Accordingly, the present obviousness assessment merely reduces Applicant’s invention into its component parts and applies a document corresponding to each component. This type of assessment clearly imports hindsight into the obviousness determination by using the invention as a roadmap. The U.S. Supreme Court cautioned against just this, again in *KSR*, stating, “A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.” *Id.* at 421, 127 S. Ct. 1742, 167 L. Ed. 2d at 724, 82 USPQ2d (BNA) at 1397 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “guard against slipping into the use of hindsight” (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412, 141 USPQ (BNA) 549 (6th Cir. 1964)))).

Following *KSR*, in *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363, 85 USPQ2d (BNA) 1641 (Fed. Cir. 2008), the Federal Circuit emphasized that “[w]e must . . . be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.” *Id.* at 1373, 85 USPQ2d (BNA) at 1648. In *Innogenetics*, conclusory assertions that it would have been obvious to a person of ordinary skill to combine prior art references were held to be vague and not helpful “in avoiding the pitfalls of hindsight that belie a determination of obviousness.” *Id.*

The Examiner’s apparent rationale for combining the cited documents is merely that each one teaches some element of the claimed invention. This is clearly insufficient for a *prima facie* case of obviousness.

Furthermore, the claims recite certain relationships involving solubility parameters (e.g., in claim 1 recites a terpolymer-bipolymer blend having a total solubility parameter (δ_T) approximately equal to a bioactive agent’s solubility parameter (δ) and wherein δ_T and δ is between $15 \text{ J}^{1/2}/\text{cm}^{3/2}$ to $25 \text{ J}^{1/2}/\text{cm}^{3/2}$; claim 13 recites the difference between the solubility parameters of said terpolymer-bipolymer blend and said bioactive agent is no greater than $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ and the total solubility parameter (δ_T) of said bioactive agent-containing terpolymer-bipolymer blend is no greater than $25 \text{ J}^{1/2}/\text{cm}^{3/2}$). There is simply no teaching or suggestion in

the cited documents to convey to one skilled in the art which polymers to select so that the polymers and bioactive agents possess the recited solubility parameter relationships. The cited documents provide no more guidance toward the subject matter of Applicant's claims than mere entry into a stockroom where a myriad of possible polymer combinations and possible polymer/bioactive agent combinations exist, wherein there is no guidance as to which polymers and bioactive agents to select in order to obtain the combinations recited in the claims.

Withdrawal of these rejections is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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